
EXAMINER'S PROPOSED AMENDMENT

DRAFT

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 10 November 2008 with Mr. Paul M. Booth, Applicants' Representative.

In the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the instant application:

1. (Currently amended) A method of preparing a biomolecule lysate, comprising the steps of:
 - (a) heating a composition comprising a formalin fixed biological sample and a reaction buffer at a temperature ~~between about~~ from 80°C ~~to and about~~ 100°C for a period of time from ~~about~~ 10 minutes to ~~about~~ 4 hours to reverse or release protein cross-linking in said biological sample, and
 - (b) treating the resulting composition with an effective amount of a proteolytic enzyme selected from the group consisting of trypsin, chymotrypsin, and endoproteinase Lys-C for a period of time from ~~about~~ 30 minutes to ~~about~~ 24 hours at a temperature ~~between about~~ from 37°C to ~~about~~ 65°C to disrupt the tissue and cellular structure of said biological sample and to liquefy said sample, thereby producing a liquid, soluble, dilutable biomolecule lysate that is suitable for protein analysis and wherein the protein content of said lysate is representative of the total protein content of said biological sample.
2. (Currently amended) The method according to claim 1, wherein said biological sample comprises a ~~substantially~~ homogeneous population of tissues or cells.

3. (Previously presented) The method according to claim 1, further comprising, prior to step (a), the step of removing any paraffin present in said biological sample by one or more methods selected from the group consisting of: adding an organic solvent; heating; heating and adding a buffer comprising Tris; and heating and adding an organic solvent.

4. (Currently amended) The method according to claim 1, further comprising, prior to step (b), the step of mechanically disrupting said biological sample by at least one technique selected from the group consisting of: manual homogenization; vortexing; and physical mixing.

5-8. (Canceled)

9. (Previously presented) The method according to claim 1, wherein said reaction buffer comprises a detergent.

10. (Previously presented) The method according to claim 1, wherein step (b) is carried out in the presence of a detergent.

11. (Currently amended) The method according to claim 9, wherein said detergent is selected from the group consisting of ~~Nonidet P40~~ NONIDET P40, SDS, ~~Tween-20~~ TWEEN 20, ~~Triton-X~~ TRITON X, and sodium deoxycholate.

12. (Currently amended) The method according to claim 10, wherein said detergent is selected from the group consisting of ~~Nonidet P40~~ NONIDET P40, SDS, ~~Tween-20~~ TWEEN 20, ~~Triton-X~~ TRITON X, and sodium deoxycholate.

13. (Canceled)

14. (Currently amended) The method according to claim 1, wherein said reaction buffer comprises Tris and has a pH in the range of ~~about~~ 1.0 to ~~about~~ 9.0.

15. (Currently amended) A method of preparing a biomolecule lysate, comprising the steps of:

(a) heating a composition comprising a formalin fixed biological sample and a reaction buffer at a temperature from 80°C to 100°C for a period of time from 10 minutes to 4 hours to reverse or release protein cross-linking in said biological sample,

(b) treating the resulting composition with an effective amount of a proteolytic enzyme selected from the group consisting of trypsin, chymotrypsin, and endoproteinase Lys-C for a period of time from 30 minutes to 24 hours at a temperature between 37°C to 65°C to disrupt the tissue and cellular structure of said biological sample and to liquefy said sample, thereby producing a liquid, soluble, dilutable biomolecule lysate that is suitable for protein analysis and wherein the protein content of said lysate is representative of the total protein content of said biological sample, and

The method according to claim 1, further comprising the step of fractionating said biomolecule lysate into distinct and separate biomolecule fractions.

16. (Previously presented) The method according to claim 15, wherein each biomolecule fraction contains distinct and separate biomolecules suitable for use in biochemical assays.

17. (Previously presented) The method according to claim 1, wherein said biological sample is selected from a group consisting of formalin-fixed tissue/cells, formalin-fixed/paraffin embedded (FFPE) tissue/cells, FFPE tissue blocks and cells from those blocks, and tissue culture cells that have been formalin fixed and or paraffin embedded.

18-39. (Canceled)

40. (Previously presented) The method of claim 15, wherein said fractionating is carried out using a method selected from the group consisting of step spin column fractionation, immunoprecipitation, gradient centrifugation, HPLC and drip column fractionation.

41. (Previously presented) The method of claim 1, further comprising assaying said biomolecule lysate using mass spectrometry.

42. (New) The method according to claim 1, wherein said reaction buffer comprises Tris and has a pH in the range of 6.0 to 9.0.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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10 November 2008